

Product & Regulatory Associates, L.L.C.

September 17, 2021

via CDX/PSP

Hope Johnson (PM-2124)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: **Aceto Dodine Technical**
EPA File Symbol 33427-XX
Application for Pesticide Registration for a New Product
PRIA Category: R334 New Manufacturing-Use Product from an
Unregistered Source of Active Ingredient with Product
Chemistry and Acute Toxicity Data with “Selective” Data Citation

PRIA Milestone Tracking E-mail Notification: jwrightch@comcast.net

Dear Hope Johnson:

On behalf of Aceto US, LLC, I am transmitting this application for pesticide registration of Aceto Dodine Technical to the U.S. Environmental Protection Agency.

Aceto Dodine Technical, EPA File Symbol 33427-XX is a manufacturing-use product used for manufacturing or formulating use only. The product contains Dodine, PC Code 44301 as the sole active ingredient with nominal concentration of 98.81% w/w.

This new manufacturing-use product is substantially similar to Dodine Technical, EPA Reg. No. 55260-4.

The complete product chemistry and acute toxicology data for this manufacturing-use product to support this registration application are provided as listed below.

The use sites on the proposed label are those listed on the Dodine Technical, EPA Reg. No. 55260-4 label.

Aceto is using the “selective” method of data support for this registration application covering the use sites listed on the proposed label. The enclosed Data Matrix forms list the appropriate data requirements for this new product registration.

September 17, 2021

Page 2 of 5

The PRIA Category is R334, for a new manufacturing-use product from an unregistered source of active ingredient with product chemistry data and use sites on substantially similar registered product. The PRIA fee is \$24,255.00.

This registration application request contains the following enclosed materials:

Volume 1 of 26

Administrative Documents

- Transmittal
- Application for Pesticide Registration (EPA Form 8750-1)
- Cover letter
- PRIA IV Fee Confirmation
 - 26TAAIC1
- Authorized Representative letter
- Confidential Statement of Formula (EPA Form 8750-4)
 - Basic dated 9/10/21
 - Alternate 1 dated 9/10/21
- Certificate with Respect to Citation of Data (EPA Form 8570-34)
- Data matrix private and public copies (EPA Form 8570-35)
- Proposed label
 - 033427-000XX.20210811.Dodine Technical Proposed Label.pdf

Volume 2 of 26

MRID 51639101 *Aceto Dodine Technical, Product Chemistry, Group A: Product Identity and Composition*, OCSPP Guidelines 830.1500, 830.1600, 830.1650, 830.1670 & 830.1750, John F. Wright, Product & Regulatory Associates, LLC, August 10, 2021, Study Number 21-PRA-Aceto-214, 86 pp.

Volume 3 of 26

MRID 51639102 *Final Report Five Batch Analysis of Dodine Technical, Volume I of II*, OCSPP Guidelines 820.1700, 830.1800, Jitendra G. Patil, Indofil Industries Limited, September 07, 2021, Study Number GLP/104/2021, 283 pp.

Volume 4 of 26

MRID 51639103 *Final Report Five Batch Analysis of Dodine Technical, Volume II of II*, OCSPP Guidelines 820.1700, 830.1800, Jitendra G. Patil, Indofil Industries Limited, September 07, 2021, Study Number GLP/104/2021, 130 pp.

Volume 5 of 26

MRID 51639104 *Final Report for: Preliminary Analysis of Dodine Technical*, OCSPP Guidelines 830.1700, Summer Theus, Analytical & Regulatory Chemistry, Inc., 2/19/16, Report Number ARC-EX-1727-009-P-1, 103 pp.

September 17, 2021

Page 3 of 5

Volume 6 of 26

MRID 51639105 *Determination of active Ingredient Content of Dodine Technical*, OCSPP Guideline 830.1800, Jayalakshmi R., Bioneds India Private Limited, May 17, 2016, Study Number BIO-ANM 171, 22 pp.

Volume 7 of 26

MRID 51639106 *Determination of Appearance (Physical State, Color, Odor) of Dodine Technical*, OCSPP Guidelines 830.6302, 830.6303, 830.6304, V.K. Patil, Indofil Industries Limited, May 5, 2021, Study Number GLP/100/2021, 18 pp.

Volume 8 of 26

MRID 51639107 *Final Report for: Physical and Chemicals Characteristics of Dodine Technical*, OCSPP Guidelines 830.6302, 830.6303, 830.6304, 830.7050, 830.7200 & 830.7300, Summer Theus, Analytical & Regulatory Chemistry, Inc., 3/30/17, Report Number ARC-EX-1990-009-P-1, 24 pp.

Volume 9 of 26

MRID 51639108 *Determination of Density, Relative Density and Specific Gravity of Dodine Technical*, OCSPP Guideline 830.7300, V.K. Patil, Indofil Industries Limited, May 7, 2021, Study Number GLP/102/2021, 22 pp.

Volume 10 of 26

MRID 51639109 *Determination of Oxidizing Properties of Dodine Technical*, OCSPP Guideline 830.6314, Jayalakshmi R., Bioneds India Private Limited, September 26, 2016, Study Number BIO-ANM 140, 31 pp.

Volume 11 of 26

MRID 51639110 *Determination of Flammability of Dodine Technical*, OCSPP Guideline 830.6315, Jayalakshmi R., Bioneds India Private Limited, September 23, 2016, Study Number BIO-ANM 139, 26 pp.

Volume 12 of 26

MRID 51639111 *Determination of Self Ignition Temperature of Dodine Technical*, OCSPP Guideline 830.6316, Jayalakshmi R., Bioneds India Private Limited, October 4, 2016, Study Number BIO-ANM 159, 30 pp.

Volume 13 of 26

MRID 51639112 *Determination of Explosive Properties of Dodine Technical*, OCSPP Guideline 830.6316, K. Sharadha Devi, RCC Laboratories India Private Limited, September 11, 2015, Study Number 5716, 33 pp.

September 17, 2021

Page 4 of 5

Volume 14 of 26

MRID 51639113 *Determination of pH (1% w/v aqueous dispersion) of Dodine Technical*, OCSPP Guideline 830.7000, V.K. Patil, Indofil Industries Limited, May 5, 2021, Study Number GLP/101/2021, 23 pp.

Volume 15 of 26

MRID 51639114 *Dodine Technical Determination of Melting Point*, OCSPP Guideline 830.7200, Jitendra G. Patil, Indofil Industries Limited, July 14, 2016, Study Number GLP/62/2016, 18 pp.

Volume 16 of 26

MRID 51639115 *Determination of Partition Coefficient of Dodine Technical*, OCSPP Guideline 830.7550, Jayalakshmi R., Bionneeds India Private Limited, October 4, 2016, Study Number BIO-ANM 135, 49 pp.

Volume 17 of 26

MRID 51639116 *Dodine Technical Determination of Solubility in Organic Solvents*, OCSPP Guideline 830.7840, Jitendra G. Patil, Indofil Industries Limited, July 28, 2016, Study Number GLP/63/2016, 19 pp.

Volume 18 of 26

MRID 51639117 *Dodine Technical Determination of Solubility in Water*, OCSPP Guideline 830.7840, Jitendra G. Patil, Indofil Industries Limited, April 27, 2017, Study Number GLP/64/2016, 47 pp.

Volume 19 of 26

MRID 51639118 *Determination of Vapour Pressure of Dodine Technical*, OCSPP Guideline 830.7950, Jayalakshmi R., Bionneeds India Private Limited, April 14, 2017, Study Number BIO-ANM 160, 93 pp.

Volume 20 of 26

MRID 51639119 *Aceto Dodine Technical, Physical and Chemical Properties – Product Chemistry Data Waiver Requests*, OCSPP Guidelines 830.6313, 830.6315, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220, & 830.7370, John F. Wright, Product & Regulatory Associates, LLC, September 10, 2021, Study Number 21-PRA-Aceto-215, 16 pp.

Volume 21 of 26

MRID 51639120 *Acute Oral Toxicity Study of Dodine Technical in Rats*, OCSPP Guideline 870.1100, Dipti A. Aswalkar, JAI Research Foundation, December 6, 2017, Study Number 401-1-01-16767, 51 pp.

September 17, 2021

Page 5 of 5

Volume 22 of 26

MRID 51639121 *Acute Dermal Toxicity Study of Dodine Technical in Rats*, OCSPP Guideline 870.1200, Dipti A. Aswalkar, JAI Research Foundation, December 5, 2017, Study Number 403-1-01-16768, 39 pp.

Volume 23 of 26

MRID 51639122 *Acute Inhalation Toxicity Study of Dodine Technical in Rats*, OCSPP Guideline 870.1300, Ramesh Verma, JAI Research Foundation, November 28, 2017, Study Number 405-1-01-16769, 66 pp.

Volume 24 of 26

MRID 51639123 *Acute Eye Irritation Study of Dodine Technical in Rabbits*, OCSPP Guideline 870.2400, Jaimish Prajapati, JAI Research Foundation, July 24, 2018, Study Number 407-1-01-16771, 66 pp.

Volume 25 of 26

MRID 51639124 *Acute Dermal Irritation Study of Dodine Technical in Rabbits*, OCSPP Guideline 870.2500, Jaimish Prajapati, JAI Research Foundation, July 17, 2018, Study Number 406-1-01-16770, 38 pp.

Volume 26 of 26

MRID 51639125 *Skin Sensitisation Study of Dodine Technical by local Lymph Node Assay in Mice*, OCSPP Guideline 870.2600, Ramesh Verma, JAI Research Foundation, March 12, 2018, Study Number 409-1-01-18837, 61 pp.

If you have any question in regard to this matter, feel free to contact me at (609) 841-8288 or JWrightCH@comcast.net.

Sincerely,



John F. Wright
Product & Regulatory Associates, LLC
Authorized Representative of Aceto US, LLC.

cc: Fred Trudwig, Jr., Aceto